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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

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THE PROCTER & GAMBLE COMPANY
PATENT DIVISION
HEALTH CARE RESEARCH CENTER
8340 MASON-MONTGOMERY ROAD
MASON, OH 45040

EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/08/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/361,542

Applicant(s)

DOBROZSI, DOUGLAS JOSEPH

Examiner

Amy E Pulliam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendment D, received December 21, 2001.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, and 33 are rejected under 35 U.S.C. 102(a) OR (b) as being anticipated by the product *Silicol*, which is manufactured by Saguna GmbH in Germany. *Silicol* is a unique gel composition which consists of water and colloidal silicic acid. The advertisement relied upon for this rejection states that when *Silicol* is taken three times a day with meals, it forms a soothing coating over the lining of the stomach and intestines. Further, it teaches that *Silicol* coats and protects the lining of the gut.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Silicol* alone, or in view of WO 98/48814 to Banning *et al.*.

The advertisement for *Silicol* does not teach that active ingredients be present in the formulation. However, it is the position of the examiner that the method as claimed is to use colloidal silica to coat the mucosal of the gastrointestinal tract. Furthermore, it is also the position of the examiner that the addition of an active agent does not affect the mucoadhesiveness of the composition. Lastly, as stated by applicant in their specification, all prior art mucoadhesive systems require polymers for the mucoadhesive properties. However, as shown by *Silicol*, it has been discovered that colloidal silicic acid has these mucoadhesive properties. Therefore, it remains the position of the examiner that the method of providing a mucoadhesive composition to the mucosal of the esophagus by swallowing a composition comprising silica is rendered obvious by the teachings of *Silicol*.

Additionally, the purpose of *Silicol* is to coat the gastrointestinal tract. The reference further teaches that this composition is useful for persons suffering from gastritis, flatulence, heartburn, nausea and diarrhea. The reason it is useful is because it coats the gastrointestinal tract, therefore absorbing toxins and irritants, and protecting the lining of the gut. It is the position of the examiner that this protection is meant to

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protect the gut from irritating active agents as well. Therefore, it would be obvious to include active agents in the present composition, as the composition would protect the gut from the active, and allow comfortable treatment.

For further emphasis, the Banning *et al.* reference is relied upon for the teaching that substances which are known to coat the gastrointestinal mucosa are known in combination with active agents. More specifically, Banning *et al.* teach that a well known approach to treating oesophageal and gastric disorders is to use a material which provides a protective coating on the mucus or mucosa of the gastrointestinal tract (p 5, l 1-4). Furthermore, Banning *et al.* teach that the agent which forms the protective coating can be combined with an active agent (p 12, l 10-14).

Although the Banning *et al.* reference relies on alginate to form the protective coating, rather than silica, this is not the reason the reference is relied upon. This reference is relied upon for the teaching that it is known in the art to coat the gastrointestinal tract in order to treat gastric disorders. Additionally, it is known to administer the mucoadhesive protective materials in combination with active agents. The advertisement for *Silicol* shows that a new material has been found which is successful in coating the gastrointestinal tract in order to protect it and treat gastric disorders. One of ordinary skill in the art would be motivated to use this new mucoadhesive material in the same manner the previously known mucoadhesive material were used, which includes in combination with active agents. The expected result would be a mucoadhesive formulation, which protects the lining of the gut, and succeeds in treating a variety of gastric disorders. Therefore, this invention as a whole

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would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
March 5, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600